SYNTHES®

K053022

JAN 23 2006

3.0 510(k) Summary

Sponsor:

Synthes (USA)
1302 Wrights Lane East
West Chester, PA 19380
(610) 719-5000

Device Name: Synthes (USA) chronOS™ - ß-TCP

Classification: Class II, 21 CFR §872.3930
Bone grafting material, synthetic

Class II, 21 CFR §880.5600
Piston Syringe

Predicate Device: Interpore IP 200 Coralline Hydroxyapatite Granules and Blocks
chronOS, Craniofacial Applications, GXP

Device Description: Synthes chronOS is a porous, osteoconductive, resorbable dental bone grafting material made from ß-Tricalcium Phosphate (TCP). chronOS features a uniform three dimensional pore structure. Pore diameters within the material range from 100 to 500 µm. chronOS is provided sterile in granules and preformed shapes (e.g. blocks, cylinders, wedges).

chronOS may be packaged with a perfusion syringe that is used to mix the bone grafting material with the patient's blood, bone marrow or saline.

Intended Use: Synthes chronOS is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region. Specifically, for the augmentation of deficient maxillary and mandibular alveolar ridges and the treatment of oral, maxillofacial and dental intraosseous defects including: ridge augmentation; sinus lifts; craniofacial augmentation; filling of defects of endodontic origin; filling of cystic defects; filling of extraction sites; filling of lesions of periodontal origin; repair of traumatic defects of the alveolar ridge; filling resection defects in bone tumors, cysts or other osseous defects; and substitute for autogenous or allogenic bone grafts.

Synthes chronOS is intended to be gently packed or placed into the site and may be combined with autogenous blood, bone marrow or saline. chronOS resorbs and is replaced with bone during the healing process.

Substantial Equivalence:	Documentation is provided which demonstrates that Synthes chronOS is substantially equivalent* to other legally marketed Synthes devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2006

Ms. Sheri L. Musgnung
Senior Regulatory Affairs Specialist
Synthes (USA)
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K053022
Trade/Device Name: Synthes (USA) ChronOS™ - ß-TCP
Regulation Number: 872.3930
Regulation Name: Tricalcium Phosphate Granules for Dental Bone Repair
Regulatory Class: II
Product Code: LPK
Dated: December 29, 2005
Received: January 3, 2006

Dear Ms. Musgnung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

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Indications for Use

510(k) Number (if known):

Device Name: Synthes (USA) chronOS™ - ß-TCP

Indications: Synthes chronOS is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region. Specifically, for the augmentation of deficient maxillary and mandibular alveolar ridges and the treatment of oral, maxillofacial and dental intraosseous defects including: ridge augmentation; sinus lifts; craniofacial augmentation; filling of defects of endondontic origin; filling of cystic defects; filling of extraction sites; filling of lesions of periodontal origin; repair of traumatic defects of the alveolar ridge; filling resection defects in bone tumors, cysts or other osseous defects; and substitute for autogenous or allogenic bone grafts.

Synthes chronOS is intended to be gently packed or placed into the surgical site and may be combined with autogenoous blood, bone marrow or saline. chronOS resorbs and is replaced with bone during the healing process.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible] General Hospital,
[illegible] Control, Dental Devices

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